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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,756

Applicant(s)

ARAUJO ET AL.

Examiner

Barbara Frazier

Art Unit

4173

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/1/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2 sheets.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The references cited in the Search Report dated 4/10/03 that are not listed on Applicant's Form 1449 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR

Art Unit: 4173

1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered.

Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

3. The disclosure is objected to because of the following informalities: at page 6, lines 9-10, the specification reads, "The concentration of TiO₂ preferably ranges from 2 to 4% by weight"; it appears that the sentence should read "2 to 40% by weight", as it reads in the parent priority application (See page 6, line 19 of Brazilian patent application PI 0200007-5).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear, from the reading of claim 1, what is encompassed by the term "oily dispersion" (line 1); is the "oily dispersion" limited to a "single oily dispersing vehicle" (line 4),

Art Unit: 4173

or is another phase present, since a “dispersion”, by definition, would include more than one phase? Furthermore, it is not clear if the “single emollient vehicle” (line 5) is present in the “single oily dispersing vehicle”, or in the “oily dispersion.”

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5, 7, 8, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lukenbach et al., U.S. Patent 5,980,871.

Lukenbach et al. disclose sunscreen compositions comprising an inorganic sunscreen compound, such as a mixture of titanium dioxide and zinc oxide, in an oil component comprising a carrier oil and at least one emollient (see col. 4, lines 28-37). The inorganic sunscreen compound is oil dispersible (col. 6, lines 34-36), and is added to the oil phase (col. 7, lines 30-34). Therefore, the composition of Lukenbach et al. anticipates the composition of the claimed invention.

Regarding the concentration of titanium dioxide present (claim 5), Lukenbach et al. teach that titanium dioxide should be present in the composition in the amount of from about 2% to about 25% (col. 6, lines 27-30). The amount is encompassed by Applicant's amount of 2 to 40%.

Art Unit: 4173

Regarding the concentration of zinc oxide present (claims 7 and 8), Lukenbach et al. teach that zinc oxide is present at 5% (Example 96, col. 13, lines 13-15). This is encompassed by Applicant's amounts of 2 to 25% and 5 to 10%.

Regarding the cosmetic composition (claim 15), Lukenbach et al. teach that "The compositions of this invention can be incorporated into various cosmetic and personal care products such as hand and body lotions, oils, ointments, lip balm products, facial cosmetics and the like." (col. 7, lines 11-15)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 4173

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 6, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al., US Patent 5,980,871.

Applicant Claims

The instant invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and having the following further limitations:

- a. the ratio between the pigments of TiO₂ and ZnO is 3:1 (claim 2);
 - b. the total concentration of powders in the dispersion ranges from 4 to 50% by weight, particularly 40% (claims 3 and 4);
 - c. the concentration of TiO₂ ranges from 30 to 35% by weight (claim 6);
 - d. the emollient is used in a concentration ranging from 45 to 65% by weight (claim 13);
- and
- e. the oily dispersion is prepared by a first step of mixing the dispersing vehicle and the emollient vehicle to form a single oily phase, followed by a step of adding, under stirring, the TiO₂ and ZnO pigments to the oily phase obtained in the first step (claim 14).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lukenbach et al. disclose sunscreen compositions comprising an inorganic sunscreen compound, such as a mixture of titanium dioxide and zinc oxide, in an oil component comprising a carrier oil and at least one emollient (see col. 4, lines 28-37). The inorganic sunscreen compound is oil dispersible (col. 6, lines 34-36), and is added to the oil phase (col. 7, lines 30-34). Titanium dioxide should be present in the composition in the amount of from about 2% to about 25% (col. 6, lines 27-30), and zinc oxide is present at 5% (Example 96, col. 13, lines 13-15). The emollient should be present in the formulation in a ratio to the [oil] carrier concentration of from about 1:1 to about 3:1, most preferably, about 2:1 (col. 6, lines 19-21). To prepare the dispersion, Lukenbach et al. teach the concurrent addition of the oil and emollient, followed by addition of titanium dioxide (see col. 7, lines 44-53).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Lukenbach et al. differ from the claimed invention because they do not specifically teach the limitations outlined as a-d, above, and because the process for preparing the dispersion is exemplified with titanium dioxide instead of a mixture of titanium dioxide and zinc oxide (see col. 7, lines 44-53).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

The limitations of the instant invention are found to be prima facie obvious over Lukenbach et al. for the following reasons:

Art Unit: 4173

a. Regarding the ratio of between the pigments of titanium dioxide and zinc oxide (claim 2), Lukenbach et al. do teach that the titanium dioxide is present in the final composition in an amount from 2% to 25% by weight (col. 6, lines 29-30) and zinc oxide is present at 5% (Example 96, col. 13, lines 14-15). Therefore, one having ordinary skill in the art at the time the invention was made would have been motivated to choose a ratio between the pigments of titanium dioxide and zinc oxide of 3:1 as a matter of routine optimization, with a reasonable expectation of success.

b and c. Regarding the amounts of titanium dioxide and zinc oxide powders (claims 3, 4, and 6), Lukenbach et al. teach that titanium dioxide is present in the final composition in an amount of 2% to about 25% (col. 6, lines 29-30) and that zinc oxide is present in an amount of 5% by weight (col. 13, lines 14-15). This appears to be comparable to the amounts claimed by Applicants, especially given that the prior art uses the flexible modifier "about". In any case, it would have been obvious to determine workable and/or optimal amounts of pigment per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

d. Regarding the amount of emollient present (claim 13), Lukenbach et al. teach that the emollient should be present in the formulation in a ratio to the carrier concentration of from about 1:1 to about 3:1, most preferably about 2:1. This appears to be comparable to the amounts claimed by Applicants, i.e., where the weight percentage **within the oily dispersion** is 45-65%, especially given that the prior art uses the flexible modifier "about". In any case, it would have

Art Unit: 4173

been obvious to determine workable and/or optimal amounts of emollient per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Holding that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”)

e. Regarding the process for preparing an oily dispersion (claim 14), Lukenbach et al. teach that both titanium dioxide and a mixture of titanium dioxide and zinc oxide are examples of the “inorganic sunscreen agent”. Therefore, a person having ordinary skill in the art at the time the invention was made would have been motivated to substitute the mixture of titanium dioxide and zinc oxide for the titanium dioxide in the process outlined in Lukenbach et al., with a reasonable expectation of success.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al., US patent 5,980,871, in further view of Choulot et al., US 2004/0191189.

Applicant Claims

The instant invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the particle size of the TiO₂ and ZnO pigments used ranges from 15 to 100 nanometers.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Art Unit: 4173

Lukenbach et al. teach that titanium dioxide should be used having a primary particle size from of less than about 300 nm in diameter (col. 6, lines 27-29). Choulot et al. teach that it is known to use a mixture of titanium dioxide and zinc oxide with a mean particle size being between 1 and 100 nanometers in a sunscreen composition (page 1, paragraph 4).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Lukenbach et al. differ from the claimed invention in claim 9 because the reference is silent with respect to whether or not the mixture of titanium dioxide and zinc oxide is in particulate form (i.e., from 15 to 100 nanometers).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

However, since Choulot et al. teach that it is known to use a mixture of titanium dioxide and zinc oxide with a mean particle size being between 1 and 100 nanometers in a sunscreen composition (page 1, paragraph 4), and since both compositions are sunscreen compositions, a person having ordinary skill in the art at the time the invention was made would have been motivated to use a mixture of titanium dioxide and zinc oxide with the size of Choulot et al. in the sunscreen composition of Lukenbach et al., with a reasonable expectation of success.

9. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al., US Patent 5,980,871, in further view of Kaplan, US Patent 5,989,529.

Applicant Claims

The instant invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the dispersing vehicle is selected from the group consisting of polyethyleneglycol and silicone esters, particularly dipolyhydroxy stearate PEG 30.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lukenbach et al. teach that the carrier oil should be selected from the group of polyether interrupted fatty acid esters (col. 5, lines 65-66). Kaplan teaches that PEG 30 dipolyhydroxystearate may be advantageously used to permit the formulation of “an improved oil-in-water sunscreen formulation having improved stability, low viscosity and cosmetic elegance.” (col. 1, lines 40-46).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Lukenbach et al. differ from the claimed invention in claims 10 and 11 because they do not specifically teach that the oil is polyethyleneglycol esters or dipolyhydroxy stearate PEG 30.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

However, since Kaplan teaches that PEG 30 dipolyhydroxystearate may be advantageously used to permit the formulation of “an improved oil-in-water sunscreen formulation having improved stability, low viscosity and cosmetic elegance”, and since both

Art Unit: 4173

compositions are drawn to sunscreen formulations, a person having ordinary skill in the art at the time the invention was made would have been motivated to choose dipolyhydroxy stearate PEG 30 as the oil in the sunscreen composition of Lukenbach et al., with a reasonable expectation of success.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al., US Patent 5,980,871, in further view of Liu et al., US Patent 5,916,544.

Applicant Claims

The instant invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the emollient is selected from the group consisting of isocetyl stearyl stearate, glycerol tri-2-ethyl hexanoate and propoxylated stearyl alcohol.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lukenbach et al. teach that the emollient may be “a conventional emollient known to those of ordinary skill in the art as useful in sunscreen products, such as...synthetic emollients such as fatty acid esters and the like” (see col. 6, lines 14-19). Liu et al. teach that Ceraphyl 791 (isocetyl stearyl stearate) is known to be used as an emollient in sunscreen compositions with titanium dioxide and zinc oxide (for example, see Examples 18 and 19, col. 6, lines 63-64 and col. 8, lines 20-21).

Art Unit: 4173

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Lukenbach et al. differ from the claimed invention in claim 12 because they do not specifically teach that the emollient is isocetyl stearyl stearate, glycerol tri-2-ethyl hexanoate, or propoxylated stearyl alcohol.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

However, since Liu et al. teach that Ceraphyl 791 (isocetyl stearyl stearate) is known to be used as an emollient in sunscreen compositions with titanium dioxide and zinc oxide, and since both compositions are sunscreen compositions, a person having ordinary skill in the art at the time the invention was made would have been motivated to choose isocetyl stearyl stearate as the fatty acid ester emollient in the composition of Lukenbach, with a reasonable expectation of success.

Pertinent Prior Art

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dederen et al., US Patent 6,831,107, teach that Estol 3609 (i.e., glycerol tri-2-ethyl hexanoate) is a known emollient in sunscreen compositions (see col. 15, lines 60-66 and col. 18, line 65).

Art Unit: 4173

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Frazier whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 8am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718, or Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

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